



Docket No. JJM-85

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Paul T. Jacobs et al.

Serial No. : 08/120,303

Art Unit: 1743

Filed : September 13, 1993

Examiner: J. Snay

For : METHOD AND DEVICE FOR VAPOR STERILIZATION ARTICLES
HAVING LUMENS

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APPEAL BRIEF

Dear Sir:

I. REAL PARTY IN INTEREST

This application has been assigned to Johnson & Johnson
Medical Inc., now Ethicon, Inc. which is a wholly owned subsidiary
of Johnson & Johnson.

II. RELATED APPEALS AND INTERFERENCES

Applicants are unaware of any related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 11 to 19, 21 and 22 are pending in the application. Claims 12 to 16, 21 and 22 have been allowed. Claims 11 and 17 to 19 stand rejected under 35 U.S.C. §112, second paragraph, which rejection forms the basis of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection mailed July 18, 2001.

V. SUMMARY OF THE INVENTION

In many vapor sterilization processes (for purposes of this application, vapor sterilization processes include most chemical sterilization processes as well as plasma sterilization processes) it has been found to be extremely difficult to sterilize the internal portions of long lumens. That is, in medical devices, the types of lumens that are present in scopes of various types. The advent of less invasive surgery has increased the use of scopes as well as medical devices having long bores. During most chemical sterilization processes, the sterilizer is pumped down or evacuated at the beginning or during the course of the sterilization process. It has been found that by providing a source of chemical sterilant at one end of the lumen, this pumping down draws the chemical sterilant through the internal bore of the lumen, thus sterilizing the

internal bore. Without this supply of chemical sterilant (antimicrobial solution), it is difficult to force the sterilant into the lumens once in the gaseous or vapor phase.

A device, according to the present invention, provides for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization. (Spec. pg. 2, lines 23 to 27) The device comprises a vessel for containing an antimicrobial solution and having an opening therein, the opening connecting to the lumen with the vessel being closed to the ambient atmosphere except through such opening. (spec., pg 2, line 24 to pg. 3, line 1; pg. 3, lines 23 to 31; pg. 12, lines 8 to 18 and Figures 1, 2 and 2A.) The vessel contains a known quantity of antimicrobial solution for vapor formation. (Spec, pg. 12, lines 21 to 28) In one aspect of the invention, the vessel contains a porous absorbent substrate for containing the antimicrobial solution. (Spec., pg. 12, lines 1 and 2). Some provision can be provided for attaching a removable closure cap to the opening of the vessel. (Spec., pg. 12, lines 2 to 4)

In one preferred embodiment, the invention comprises a device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization, with the device including a vessel including a cartridge for containing a known quantity of antimicrobial solution and having an opening therein. (Spec., pg. 2, lines 23 to 27; pg. 12, lines 8 to 18; and Figure 2A) The vessel includes provision for connecting the opening of the cartridge to the lumen with the cartridge being closed to the ambient atmosphere except through such opening and containing a known quantity of antimicrobial solution. (Spec.,

page 12, lines 8 to 28 and Figure 2A). The cartridge releasably attaches to the vessel via another opening in the vessel. (Spec., pg. 12, lines 15 to 20 and Figure 2A)

VI. ISSUES FOR APPEAL

Whether claims 11 and 17 to 19 have been improperly rejected under 35 U.S.C. § 112, second paragraph?

VII. GROUPING OF THE CLAIMS

For purposes of this appeal only, claims 11, 18 and 19 stand together and claim 17 stands alone.

VII. ARGUMENT

The Examiner has improperly rejected claims 11 and 17 to 19 under 35 U.S.C. §112, second paragraph upon the contention that they are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 11 includes the limitation "means for connecting said opening of said vessel to said lumen said vessel being closed to the ambient atmosphere except through such opening." Claim 17 contains the similar limitation, "means for connecting said opening of said cartridge to said lumen said cartridge being closed to the ambient atmosphere except through such opening." The Examiner contends that the specification lacks corresponding structure for a means for connecting the opening of the vessel to the lumen and the opening of the cartridge to the lumen for claim 11 and 17 respectively. Applicants respectfully

submit that the application contains this structure and meets the statutory requirements of 35 U.S.C. §112, second paragraph.

MPEP §2181.III(B)(1) states "If one skilled in the art would be able to identify the structure, materials or acts from the description in the specification for performing the recited function, then the requirements of 35 U.S.C. 112, second paragraph are satisfied. See *Dossel*, 115 F.3d at 946-947, 42 USPQ 2nd at 1885" One of skill in the art can clearly see from Applicants' specification how the openings of the vessels and cartridges connect to the lumen.

With regard to claim 11, it can easily be described with reference to Figures 1 or 2, and thus sufficient structure can be found in the specification and drawings. For example, the device shown in Figure 1 is a device for delivering an antimicrobial vapor to the lumen of an article during solution vapor sterilization. The device comprises a vessel which may be the vessel 14 indicated in the specification and shown in Figure 1. Additionally with reference to Figure 2, the vessel is indicated with numeral 34 and again is the containing device. The difference between Figure 2 and Figure 2A will be described below. The vessel is for containing an antimicrobial solution and has an opening therein. It is easily seen that there is an opening indicated by 24 in Figure 1 and also an opening indicated by 32 in Figure 2. Claim 11 continues by requiring "means for connecting said opening of said vessel to said lumen." It further requires that the vessel be closed to the ambient atmosphere except through the opening, and that the vessel contains a known quantity of antimicrobial solution for vapor formation. It is easily seen

that the vessel 14 is open only through the opening 24 and that the vessel 34 is open only through the opening 32. The opening 32 is surrounded by an elastomeric material which attaches the opening to the lumen of the device. The vessel 14 is connected through the expandable sheath 16 in a similar fashion. Thus, there is sufficient structural provision for "means for connecting said opening of said vessel to said lumen". It is clear that the vessel is either the bottle-shaped vessel indicated by numeral 14 in Figure 1, or the tumbler-shaped vessel 34 indicated in Figure 2. One of ordinary skill in the art could hardly be confused.

In Figure 2A the substrate 42 which contains the antimicrobial solution in Figure 2 has been replaced by an opening that receives a cartridge having a substrate. The cartridge 47 attaches to the bottom of the device. Once the cartridge is attached to the device, the entire device creates the "vessel" of the claims. Thus, the vessel is structurally provided for in Figure 2A as called for in Claim 11. There is further provision that the vessel, which is comprises of the cartridge 47 and the connection portion attached thereto and having the elastomeric rings 38 and 40 contained therein form the vessel. It is interesting to note that the specification specifically notes in Figure 2 that the numeral 34 is the vessel. This reference numeral points to the tumbler-shaped device of Figure 2. However, that reference numeral is not used in Figure 2A to indicate solely the attachment device at the top of the cartridge. Rather the entire device, cartridge and attachment device make up the vessel as called for in the claim. Thus the vessel (through the cartridge) contains a known quality of antimicrobial solution for vapor formation and also includes "means for connecting said

opening of said vessel to said lumen" through the elastomeric rings 38 and 40. Thus, the structural components of the means plus function language in the claims are fully set forth in the specification.

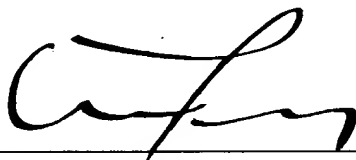
The Examiner has further rejected claim 17 under 35 U.S.C. §112, second paragraph on the grounds that the claim language defines the vessel to include a cartridge while the specification defines the vessel and the cartridge to be separate entities. The concept of the vessel forming a part of the cartridge as shown in Fig. 2A would not be confusing to one of ordinary skill in the art. Razors can include razor blades, pens can include disposable ink cartridges and the fact that this forms a portion of the overall structure would not confuse.

The Examiner also finds confusing the language "having an opening therein." However that language must be taken into context with what follows, "said vessel including means for connecting said opening of said cartridge to said lumen." Fig. 2A clearly shows opening 32 for connection through the lumen. The Examiners' confusion appears to stem from his refusal to concede that the vessel can include a cartridge as a disposable portion thereof. Thus, to the extent that Applicants have shown that it is not confusing to one of skill in the art to conceive of the vessel including the cartridge, the Examiners' reasoning as regards the "opening therein" is moot.

Applicants respectfully submit that the claims on appeal meet the statutory of requirement of 35 U.S.C. §112, second paragraph

• and request that the rejections be withdrawn and that the patent proceed onto issuance.

Respectfully submitted,



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APPENDIX
CLAIMS ON APPEAL

11. A device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization, said device comprising a vessel for containing an antimicrobial solution and having an opening therein, and means for connecting said opening of said vessel to said lumen said vessel being closed to the ambient atmosphere except through such opening said vessel containing a known quantity of antimicrobial solution for vapor formation.

17. A device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization, said device comprising a vessel including a cartridge for containing a know quantity of antimicrobial solution and having an opening therein, said vessel including means for connecting said opening of said cartridge to said lumen said cartridge being closed to the ambient atmosphere except through such opening said cartridge containing a known quantity of antimicrobial solution for vapor formation wherein said means for connecting includes an opening for releasably attaching said cartridge containing a know quantity of antimicrobial solution to form said vessel.

18. The device of Claim 11 wherein said vessel contains a porous absorbent substrate for containing said antimicrobial solution.

19. The device of Claim 11 wherein the vessel has means for attaching a removable closure cap to the opening thereof.